

Award Number:  
W81XWH-10-2-0133

TITLE:  
Treatment of Early Post-op Wound Infection after Internal Fixation

PRINCIPAL INVESTIGATOR:  
William Obrebskey, M.D.

CONTRACTING ORGANIZATION:  
Vanderbilt University Medical Center  
Nashville TN 37203

REPORT DATE:  
October 2016

TYPE OF REPORT:  
Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. <b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</b>					
1. REPORT DATE (DD-MM-YYYY) October 2016		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 15Sep2015 - 14Sep2016	
4. TITLE AND SUBTITLE Treatment of Early Post-Op Wound Infection after Internal Fixation				5a. CONTRACT NUMBER W81XWH-10-2-0133	
				5b. GRANT NUMBER W81XWH-10-2-0133	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)  William Obremskey  email: william.obremskey@vanderbilt.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Vanderbilt University Medical Center 3319 West End Ave, Suite 100 Nashville TN 37203				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT  Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to (1) evaluate the effect of treatment of post-op wound infection in long bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after fixation of fractures or joint fusion.					
15. SUBJECT TERMS Nothing Listed					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT  UU	18. NUMBER OF PAGES  5	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

## Table of Contents

	<u>Page</u>
Introduction.....	4
<b>Body.....</b>	<b>4</b>
<b>Key Research Accomplishments.....</b>	<b>5</b>
<b>Reportable Outcomes.....</b>	<b>5</b>
<b>Conclusion.....</b>	<b>5</b>
<b>References.....</b>	<b>5</b>
<b>Appendices.....</b>	<b>5</b>

## **Annual Report: “Treatment of Early Post-Op Wound Infection after Internal Fixation” Sept. 15, 2015 - Sept. 14, 2016**

### **Introduction:**

Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to investigate the efficacy of oral (per os, (PO)) antibiotic therapy versus intravenous (IV) antibiotics in the treatment of acute infection after fixation of fractures or fusion of joints.

Study Specific Aim # 1: To evaluate the effect of treatment of post-op wound infection in bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks.

Study Specific Aim # 2: To build and validate a risk prediction model for failure of treatment of early post-op wound infections after fixation of fractures and joint fusions.

### **Body:**

During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to recruitment and enrollment into the study. As of October 1, 2016, a total of 1143 patients have been screened for eligibility, and of these, 503 were eligible. Of the 503 eligible patients, 128 (25% of eligible) were consented and enrolled into the RCT; 87 (17% of eligible) were consented and enrolled into the observational arm. We have now reached 48.5% of our total enrollment. Seventy-five patients have completed the study.

Task 1	Months 1-6	Completed
Task 2	Months 6-72	Completed
Task 3	Months 12-84	Enrollment – in progress
Task 4	Months 48-84	Complete Follow up visits- in progress
Task 5	Months 84-96	Conduct analysis and final report- in progress

**NEXT STEPS:**

- Continue enrollment through September 2017.
- Complete follow up visits by September 2018.
- Begin data analysis once we reach 50% of enrollment goal as per protocol
- Encourage each site to enroll 6 patients over the next 12 months to meet enrollment goals
- Develop reports related to project deliverables for Consortium

**Key Research Accomplishments:**

- We have reached 48.5% of our enrollment goals
- 75 patients have completed the study
- The implementation of the observation arm has increased our enrollment rate.

**Reportable Outcomes:**

There were 32 serious adverse events (SAEs) reported during this reporting period. Twenty-six events were related to abnormal laboratory results and each determined by the medical monitor to be unrelated to study participation. Two patients experienced worsening/new infections. The remaining four consisted of allergic reaction, thrombosis of PICC line, exostosis and erythema. The medical monitor reviewed all SAEs and determined that no further action was required.

**Conclusion:**

None

**References:**

None

**Appendices:**

N/A